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## REMARKS

### Status Summary

Prior to entry of the present amendment, Claims 1-10 were pending in the present application. Claims 1-10 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Further, Claim 2 has been objected to, as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Finally, Claims 1 and 3-9 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Published U.S. Patent Application No. 2003/0068825.

In the present amendment, applicants have canceled claims 1 and 3-9 and have amended Claim 2 to more particularly recite the subject matter claimed therein. No new matter has been added.

### Claim Rejection - 35 U.S.C. § 112

Claims 1-10 stand rejected by the Patent Office under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Patent Office has rejected Claims 1-10 under 35 U.S.C. § 112, second paragraph as indefinite because the Patent Office alleges the structures of the compounds being claimed are unclear. The Patent Office argues with respect to Formulas II and III and the -NH-X- groups, that when X is an amino acid sequence, it is unclear if the sequence is oriented in the conventional direction (N-terminus on left

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side of formula), or with the C-terminus at the left-hand side. The Patent Office asserts groups Y and Z are also indefinite for similar reasons.

In response and without acquiescing as to the correctness of the Patent Office's rejection of the claims, applicants note that Claims 1 and 3-9 have been canceled and Claim 2 has been amended to independent form by the present amendment. Since all claims reciting Formulas II and III have been canceled, applicants respectfully submit that aspects of the rejection under 35 U.S.C. § 112, second paragraph related to Formulas II and III have been rendered moot. Applicants therefore respectfully request withdrawal of the rejection.

The Patent Office has also rejected Claims 1 and 2 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Patent Office asserts that it is not possible to correspond the generic formulas recited in Claim 1 with the specific examples recited in Claim 2. Specifically, the Patent Office asserts it is unclear as to how the compounds in Claim 2 should be interpreted with regard to the terminal lysine and ornithine residues. The Patent Office asserts it is unclear as to whether the compounds of Claim 2 should be interpreted to mean that the ornithine or lysine residues at the ends of the compounds are intended to include groups in addition to the side chains of these compounds or that the side chains are shown modified.

Applicants respectfully traverse the Patent Office's interpretation of the compounds recited in Claim 2 and submit that the specific compounds recited in Claim 2 were in fact encompassed by the generic formulas recited in Claim 1. When Claim 2 is read in light of Claim 1, it is clear that the group at the end of the claimed

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compounds (affixed to the lysine or ornithine) is the lysine or ornithine side-chain, derivatized by an iodoacetamide group. This reading of the compounds of Claim 2 agrees with Claim 1, in that Link is selected from the group consisting of Lys- $\epsilon$ -iodoacetamide, and Orn- $\delta$ -iodoacetamide. Also, the specification teaches that "[w]hen an amino acid group of a compound is derivatized by the iodoacetamide group, the iodoacetamide group is chemically bound to the side-chain amino group of the amino acid moiety." Specification at page 26, paragraph [0065] (emphasis added).

However, in an effort expedite prosecution, applicants have canceled Claim 1 and amended Claim 2 to independent form. Further, applicants have amended Claim 2 to recite "-Lys- $\epsilon$ -iodoacetamide" or "-Orn- $\delta$ -iodoacetamide" rather than "K-CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>-NH-C(O)-CH<sub>2</sub>I" or "Orn-CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>-NH-C(O)-CH<sub>2</sub>I", respectively. Applicants respectfully submit the scope of the claimed subject matter has not been altered by the amendment, as both forms of the claim language recite the same entity, that is, either a lysine or an ornithine residue modified with an iodoacetamide at the terminal amino group of the side chain. Specific support for the amendment can be found in the specification at page 26, paragraphs [0065] and [0066]. Therefore, no new matter has been added. As such, applicants respectfully submit Claim 2 is not indefinite and request withdrawal of this rejection of Claim 2 under 35 U.S.C. § 112, second paragraph.

The Patent Office has also rejected Claim 10 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Patent Office asserts that it is unclear if the

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iodoacetamide groups are attached to the side chains of the glycine, alanine, aminobutyric acid, and valine residues, or if they are attached to the C-termini of these residues.

Applicants respectfully traverse the Patent Office's interpretation of the compounds recited in Claim 10 and submit that the specific compounds recited in Claim 10 clearly define the claimed subject matter. Specifically, Claim 10 clearly recites that the iodoacetamide group is attached to the C-termini of the amino acid residues and  $\gamma$ -aminobutyric acid. In particular, the first compound listed in Claim 10 includes a glycine attached to the iodoacetamide group. As the side chain of glycine (hydrogen) is not reactive, it is not chemically possible to attach an iodoacetamide to the side chain. In order for the iodoacetamide to be attached to the side chain of glycine, the entire side chain would need to be removed and the iodoacetamide attached directly to the  $\alpha$ -carbon of the amino acid, at which point the residue would no longer be glycine. Therefore, the only logical connection for the iodoacetamide to the amino acid residue in this case is at the C-termini. In Claim 10, since the iodoacetamide group is attached to the C-termini of the amino acids rather than the side chains, the structure is drawn as a direct link to the terminal amino acid residue. As such, applicants respectfully submit Claim 10 is not indefinite and request withdrawal of this rejection of Claim 10 under 35 U.S.C. § 112, second paragraph.

In light of the above remarks with regard to the rejections of pending Claims 2 and 10 under 35 U.S.C. § 112, second paragraph, applicants respectfully submit the rejections have been obviated, and request withdrawal of the rejections of Claims 2

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and 10 as indefinite. Applicants also respectfully submit the claims are now in proper condition for allowance and earnestly request a Notice of Allowance to that effect.

#### Claim Objection

The Patent Office has objected to Claim 2 under 37 C.F.R. § 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. As previously noted, applicants have canceled Claim 1 and amended Claim 2 to independent form. As such, applicants respectfully submit the objection has been rendered moot and therefore request withdrawal of the objection to Claim 2.

#### Claim Rejection – 35 U.S.C. § 102(e)

Claims 1 and 3-9 have been rejected by the Patent Office under 35 U.S.C. § 102(e) as being anticipated by Published U.S. Patent Application No. 2003/0068825 to Washburn et al. (hereinafter referred to as "Washburn et al."), claiming priority to U.S. Provisional Patent Application No. 60/305,169. The Patent Office argues Washburn et al. teaches compounds having the same structures recited in Claims 1 and 3-9.

In an effort to expedite prosecution, and without acquiescing as to the correctness of the Patent Office's rejection of the claims, applicants have canceled rejected Claims 1 and 3-9 and amended Claim 2 to independent form. At page 4 of the present Official Action, the Patent Office affirms Washburn et al. is not prior art

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against Claims 2 and 10. Therefore, allowance of Claims 2 and 10 is respectfully requested.

#### CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

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DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

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1392/10/3/2/2 AAT/JD/acy

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